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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/974,798	10/12/2001	Ellen M. Heath	770047.402	7769

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EXAMINER
OLSON, ERIC

ART UNIT	PAPER NUMBER
1623	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/974,798	HEATH ET AL.	
	Examiner	Art Unit	
	ERIC S. OLSON	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 February 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-32,34-36,38-43,45-59,61-63 and 65-71* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-27,30-32,34-36,38-43,45-54,57-59,61-63 and 65-71* is/are rejected.

7)☒ Claim(s) *28,29,55 and 56* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

This office action is a response to applicant's communication submitted February 5, 2010 wherein the rejections of record in the previous office action are traversed. This application was filed October 12, 2001, and makes no priority claims.

Claims 21-32, 34-36, 38-43, 45-59, 61-63, and 65-71 are pending in this application.

Claims 21-32, 34-36, 38-43, 45-59, 61-63, and 65-71 as amended are examined on the merits herein.

Applicant's arguments, submitted February 5, 2010, with respect to the rejection of instant claims 28, 29, 55, and 56 under 35 USC 103(a) for being obvious over Deggerdal et al. in view of Nargessi in view of Heath, have been fully considered and found to be persuasive to remove the rejection as one of ordinary skill in the art would not have had any reason to use such high concentrations of alkali metal salt with a polyester support, as opposed to a magnetizable cellulose support. Therefore the rejection is withdrawn.

The following rejections of record in the previous office action are maintained:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

> invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 21-27, 30-32, 34-36, 38-40, 42, 43, 45-54, 57-59, 61-63, 65-67, and 69-71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Deggerdal et al. (PCT international publication WO96/18731, of record in previous office action) in view of Nargessi. (US patent 6855499, of record in previous action).

Deggerdal et al. discloses a method of isolating a nucleic acid, including RNA, by treating the nucleic acid with detergent and allowing it to bind to a solid support. (p. 5, paragraphs 2-4) The nucleic acid can be isolated from any material containing nucleic acids, including the microorganisms, clinical samples, and environmental samples described in instant claims 23-26 (p. 6, paragraphs 2-3) including plant cells, mycoplasms, protozoa, bacteria, fungi, and viruses, for example, and can include semi-pure materials as described in instant claim 21. The binding step can be preceded by a lysing step to lyse the biological material. (p. 6, last paragraph) Detergents suitable for

use in this invention include any detergent, including non-ionic detergents. (p. 7, last paragraph) Additionally, a source of monovalent cations in a concentration of 0.1-1M can be included to increase nucleic acid capture (p. 8, second paragraph) along with a chelating agent such as EDTA. (p. 8, third paragraph) Several examples are provided of lysis solutions in which the monovalent cation is LiCl of up to 0.5M and the solution is buffered at pH 7.5, which is greater than 7. (p. 8, bottom of page) The solid support can be made of any well known solid support material, including non-silica materials such as glass, latex, or a polymeric material, and can be in various physical forms including tubes, plates, or wells. (p. 9, paragraphs 2-3) More than one solid support can be used. (p. 13, second paragraph) After the lysis and binding steps, washing and elution steps can be further performed to wash and isolate the nucleic acid. (p. 12, paragraphs 2-4) Examples are given in which all of the steps (a)-(e) of instant claim 21 are performed, for example, example 1 on p. 19. Binding is described to take place in a micorcentrifuge tube in example 6. (p. 23, lines 20-26)

Deggerdal et al. does not disclose a method in which lithium chloride is included in the lysis solution at a concentration of 4-10M or a method using cellulose as the solid support.

Nargessi discloses a method whereby nucleic acids are induced to absorb to a paramagnetic solid support such as paramagnetic cellulose-coated beads. (column 1, lines 45-52) Adsorption to solid support is facilitated by high concentrations of polyethylene glycol and salts. (column 1, lines 64-67) Salts useful in this method include

various alkali and alkaline earth metal chlorides such as lithium chloride. (column 4, lines 8-12) Generally, the salt can be present in up to about 5M. (column 4 lines 19-20)

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the disclosure of Deggerdal et al. by using a cellulose solid support for the purification and by adding 4-5M of lithium chloride to the lysis/binding buffer. One of ordinary skill in the art would have been motivated to modify the invention in this manner because Nargessi discloses that these concentrations of lithium chloride facilitate the binding of nucleic acid to the solid support, and because Nargessi explicitly suggests using cellulose as the solid support in the purification procedure. One of ordinary skill in the art would reasonably have expected success because adjusting the concentration of one component of a known mixture within the range disclosed by the prior art (i.e. choosing the upper range of 4-5M from the broad range of 0.25-5M) is within the ordinary and routine skill in the art. Moreover, the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists. See *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990). See MPEP § 2144.05 [R-1].

Therefore the invention taken as a whole is *prima facie* obvious.

Response to Argument: Applicant's arguments, submitted February 5, 2010, with respect to the above ground of rejection, have been fully considered and not found to be persuasive to remove the rejection. Applicant argues that Deggerdal et al. teaches away from combination with Nargessi because Deggerdal et al. teaches that increased viscosity (i.e. from DNA contamination) is undesirable in the preparation, and

the method of Nargessi requires adding polyalkylene glycol to the sample. Applicant further argues that Deggerdal et al. discloses the undesirability of viscous solutions throughout the purification process and not merely in the purified sample. However, the contamination described by Deggerdal et al. as being undesirable is the presence of DNA and chaotropic agents in the initial sample, which can impart undesirable viscosity to the sample and furthermore can contaminate the final product. The method of Nargessi et al., by contrast, involves the addition of polyethylene glycol during the binding step when the nucleic acid is bound to the solid phase and its removal after the washing step. The polyethylene glycol is only present during the binding and washing steps. The teachings of Deggerdal et al. regarding the undesirability of viscosity-increasing agents concerns prior art methods in which chaotropic agents are added to the sample during the lysis step. Deggerdal et al. specifically discusses the adverse consequences of using chaotropic agents and suggests an alternative lysis procedure that avoids chaotropic salts, clearly teaching that viscosity-increasing agents such as chaotropic agents should be avoided during this step. By contrast, Deggerdal et al. discusses binding and washing steps in only the most generic terms. (see pp. 9-12 discussing solid supports and washing steps) A broad range of prior art supports and procedures are encompassed and no warning is given about adding polyalkylene glycol or any other viscous agent despite such agents being used in the art for binding nucleic acids to the solid phase. About these steps, the only problem identified by Deggerdal et al. that could possibly impact the use of polyethylene glycol is that at high viscosity the beads are not effectively attracted by the magnet, resulting in increased risk for DNA

contamination, both for beads and other solid phases, and lower yields. Nargessi, by contrast, is specifically directed to magnetizable cellulose and to binding and washing steps using magnetizable cellulose as a solid support. The presence of polyalkylene glycol is shown by Nargessi et al. to actually improve the effectiveness of the binding and washing steps. One of ordinary skill in the art would not have regarded the presence of polyethylene glycol in the binding and washing steps of Nargessi et al. to be a problem, but rather to be a solution to the problem identified by Nargessi et al., namely allowing the use of magnetizable cellulose as a solid support, with the consequent avoidance of the costly and hazardous steps needed to prepare other prior art solid supports.

In conclusion, Deggerdal et al. describes in detail a specific method for cell lysis in which it is important to avoid contamination by DNA or chaotropic salts, and goes on to essentially say that any prior art binding and washing procedures can be used with the samples thus prepared. Nargessi et al., on the other hand, describes in detail a specific solid support and associated binding and washing steps to be used with this solid support, which describe polyethylene glycol as a desirable component in these steps for enhancing binding of nucleic acids to the solid support. Under these circumstances, one of ordinary skill in the art would not take Deggerdal as an authority on solid support columns or on binding and washing conditions because these things are only described in passing in the reference. Rather the vague suggestion that highly viscous solutions of chaotropic salts could interfere with magnetic capture of the solid support would not be sufficient to overrule the clear teaching of Nargessi et al. that

polyethylene glycol does not compromise the use of magnetizable cellulose, thereby motivating one of ordinary skill in the art to use a lysis step free of chaotropic salts and then to load the sample onto a magnetizable cellulose column in the presence of polyethylene glycol. Therefore the rejection is deemed proper and made **FINAL.**

Claims 41 and 68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Deggerdal et al. (PCT international publication WO96/18731, of record in previous office action) in view of Nargessi. (US patent 6855499, of record in previous action) as applied to claims 21-27, 30-32, 34-36, 38-40, 42, 43, 45-54, 57-59, 61-63, 65-67, and 69-71 above, and further in view of the Calbiochem 2000-2001 reagent catalog. (of record in previous action, herein referred to as Calbiochem)

The disclosure of Deggerdal et al. in view of Nargessi is discussed above. Deggerdal et al. in view of Nargessi does not disclose a method in which the detergent in the lysis buffer is a triton or tween detergent.

Calbiochem discloses various triton (octylphenoxypolyethoxyethanol, p. 541) and tween (polysorbate, polyoxyethylene sorbitan monolaurate, p. 546) nonionic detergents. These detergents are reasonably considered to fall within the scope of nonionic detergents included in the teaching of Deggerdal et al.

It would have been obvious to one of ordinary skill in the art at the time of the invention to use triton or tween detergents in the lysis/binding solution of Deggerdal et al. in view of Nargessi. One of ordinary skill in the art would have been motivated to use these detergents because Deggerdal et al. already discloses that nonionic

detergents in general can be used in the lysis buffer. One of ordinary skill in the art would reasonably have expected success because Deggerdal et al. teaches that any detergent can be used successfully, and selecting a particular detergent is well within the ordinary and routine level of skill in the art.

Therefore the invention taken as a whole is *prima facie* obvious.

Response to Argument: Applicant's arguments, submitted February 5, 2010, with respect to the above ground of rejection, have been fully considered and not found to be persuasive to remove the rejection. Applicant's arguments are the same as those made against the rejection over Deggerdal et al. in view of Nargessi alone and are not found persuasive for the same reasons. Therefore the rejection is maintained and made **FINAL**.

Conclusion

Claims 21-27, 30-32, 34-36, 38-43, 45-54, 57-59, 61-63, and 65-71 are rejected. Claims 28, 29, 55, and 56 are objected to for depending from a rejected base claim but would be allowable if rewritten in independent form incorporating all the limitations of the rejected base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ERIC S. OLSON whose telephone number is (571)272-9051. The examiner can normally be reached on Monday-Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on (571)272-0627. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric S Olson/
Examiner, Art Unit 1623
4/12/2010